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January 16, 2004

Office of Special Nutritionals (HFS-450)  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
200 C Street, S. W.  
Washington, D. C. 20204

FEB 06 2004

Dear Sir/Madam:

I have enclosed notification forms that are intended to comply with Section 6 of the Dietary Supplement Health and Education Act of 1994 and Rule 21 C.F.R. §101.93. A dietary supplement called NutriClean™ is discussed. I have listed the structure-function statements found on the product label and associated support literature, and have identified the product ingredients that are the subject of the statements.

Thank you.

Sincerely,

James L. Wilmer, Ph. D.  
Director, Scientific Affairs

Enclosures: 1 original and 2 copies

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**NOTIFICATION PURSUANT TO  
SECTION 6 OF DSHEA  
AND RULE 21 CFR §101.93**

This notification is being filed on behalf of **Market America, Inc.** which is the **distributor** of the product bearing the statements identified in this notification. Its business address is **1302 Pleasant Ridge Road, Greensboro, NC 27409**. This notification is being made pursuant to Section 6 of DSHEA and Rule 21 CFR §101.93. The dietary supplement product on whose label or labeling the statements appear is **NutriClean™**.

The text of each structure-function statement for which notification is now being given is:

**Statement 1:** “When taken as directed each evening, the NutriClean™ Digestive and Colon Maintenance System cannot only provide you with a proactive means to ensure better colon health, but several associated benefits as well.” — Brochure

**Statement 2:** “Each eight-ounce NutriClean™ Fiber Powder drink provides 10 grams of soluble and insoluble fiber to promote normal bowel movements two to three times per day.” —Brochure

**Statement 3:** “NutriClean™ Fiber Powder can also serve to promote circulatory health and healthy blood sugar levels.” —Brochure

**Statement 4:** “A serving of this (NutriClean™ Fiber) provides 1.5 billion healthful microorganisms shown in studies to reduce lactose intolerance, balance the bowel by reducing diarrhea and relieving constipation, freshen breath and enhance immunity.” —Website

**Statement 5:** “NutriClean™ Fiber combines soluble fiber ingredients that aid in maintaining heart health, increasing peristalsis of the bowel, reducing blood sugar levels and enhancing colonic health.” —Package Insert

**Statement 6:** “NutriClean™ HepatoCleanse capsules consist of natural botanicals and nutrients that can help to maintain a healthy liver.” —Brochure and Package Insert

**Statement 7:** “NutriClean™ Release Tablets are composed of natural botanicals that can help to gently enhance peristalsis and cleanse the bowel.” —Brochure and Package Insert

**Statement 8:** “Market America’s NutriClean™ Digestive and Colon Maintenance System is a seven-day cleansing and detoxification system that is designed to optimize your digestive tract health by providing select nutrients and botanicals that cleanse and mildly purge the body of accumulated and potential toxins.” —Website

The following summary identifies the dietary ingredients or supplements for which a statement has been made:

<b>Statement Number(s)</b>	<b>Identity of Dietary Ingredient or Supplement That Is the Subject of the Statement</b>
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- |        |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
|--------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1.- 5. | NutriClean™ Fiber Powder is composed of the following ingredients: L-glutamine, NutriClean fiber blend: soy fiber, soluble fiber complex, alfalfa leaf, beet root fiber, flax seed fiber, guar gum, inulin, oat bran, and psyllium seed husk; probiotic blend: <i>Lactobacillus acidophilus</i> , <i>Lactobacillus plantarum</i> , <i>Lactobacillus sporogenes</i> (Lactospore® brand encapsulated <i>L. sporogenes</i> ), <i>Bifidobacterium bifidum</i> , <i>Lactobacillus casei</i> ; other ingredients include: citric acid, natural flavors, acesulfame potassium, silica and sucralose |
| 6.     | NutriClean™ HepatoCleanse is composed of the following ingredients: proprietary blend: milk thistle seed powder and extract (40 mg silymarin), N-acetyl-L-cysteine, <i>Schizandra chinensis</i> fruit extract, dandelion root, yellow dock root, garlic bulb, hawthorn berry, burdock root, ginger root, hyssop aerial parts, red clover flower, licorice root, barberry root, rosemary herb (aerial parts), bayberry root bark, green tea leaf extract and curcumin root extract; other ingredients include: gelatin, calcium sulfate, magnesium stearate and silica                        |
| 7.     | NutriClean™ Release is composed of the following ingredients: Proprietary blend: rhubarb root, buckthorn bark, <i>Cascara sagrada</i> bark extract (20% hydroxyanthracene derivatives calculated as cascarioside A), gentian root, anise seed, fennel seed, black walnut bark, Oregon grape root, <i>Scutellaria</i> root extract, goldenseal aerial parts and peppermint leaf; other ingredients include: dicalcium phosphate, microcrystalline cellulose, croscarmellose sodium, stearic acid, silica, magnesium stearate and pharmaceutical glaze                                         |
| 8.     | NutriClean™ Digestive and Colon Maintenance System is composed of: NutriClean™ Fiber, NutriClean™ HepatoCleanse Capules and NutriClean™ Release Tablets                                                                                                                                                                                                                                                                                                                                                                                                                                      |

The following identifies the brand name of each supplement for which a statement is made:

<u>Statement Number(s)</u>	<u>Brand Name</u>	<u>Label or Labeling</u>
1.-8.	NutriClean™	Brochure, Package Insert and Website

I, **James L. Wilmer**, am authorized to certify this Notification on behalf of **Market America, Inc.** I certify that the information presented and contained in this Notification is complete and accurate, and that **Market America, Inc.** has substantiation that each structure-function statement is truthful and not misleading.

Date Signed: January 4<sup>th</sup>, 2004

By: James L. Wilmer  
James L. Wilmer, Ph. D.  
Director, Scientific Affairs  
Market America, Inc.